FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Antimicrobial Drugs Advisory Committee Meeting and the Drug Safety and Risk Management Advisory Committee
Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland
FDA White Oak Campus, 10903 New Hampshire Avenue
November 5, 2015

AGENDA

The committees will discuss the risks and benefits of the systemic fluoroquinolone antibacterial drugs for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis in patients who have chronic obstructive pulmonary disease, and uncomplicated urinary tract infections in the context of available safety information and the treatment effect of antibacterial drugs in these clinical conditions.

8:00 a.m.	Call to Order and Introduction of Committee	**CAPT Monica Parise, MD** Chairperson, AMDAC
8:10 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh.** Designated Federal Officer, AMDAC
8:15 a.m.	FDA Introductory Remarks	**Sumati Nambiar, MD, MPH** Division Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	**FDA PRESENTATIONS**	
	ABS, ABECB-COPD, and uUTI Antibacterial Drug Treatment Effects	**Joseph Toerner, MD, MPH** Deputy Director for Safety DAIP, OAP, OND, CDER, FDA
	Oral Fluoroquinolone Utilization Patterns	**LT Travis Ready, PharmD** Drug Use Analyst Division of Epidemiology II (DEPI-II), Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Epidemiology of Selected Fluoroquinolone-Associated Adverse Reactions – A Literature Review	**LCDR James Phillip Trinidad, MPH, MS** Epidemiologist DEPI-II, OPE, OSE, CDER, FDA
	"Fluoroquinolone-Associated Disability" (FQAD) Cases in Patients Being Treated for Uncomplicated Sinusitis, Bronchitis, and/or Urinary Tract Infections	**Debra Boxwell, PharmD** Safety Evaluator Division of Pharmacovigilance II OPE, OSE, CDER, FDA
9:45 a.m.	Clarifying Questions to the Presenters	
10:00 a.m.	**BREAK**	

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AGENDA (cont.)

10:15 a.m.	**INDUSTRY PRESENTATIONS**	
	Introduction	**Melissa Tokosh** Director, Global Regulatory Affairs Established Products Janssen Research & Development, LLC
	Medical Need for Fluoroquinolones	**Lionel A. Mandell MD, FRCPC, FRCP [LOND]** Professor Emeritus Department of Medicine, McMaster University Hamilton, Ontario, Canada
	Appropriate Role for Fluoroquinolones	**Jeff Alder, PhD** Senior Director, Global Clinical Development Anti-Infectives/Primary Care Bayer HealthCare Pharmaceuticals Inc.
	Safety of Fluoroquinolones	**Susan C. Nicholson, MD, FIDSA** Vice President Safety Surveillance and Risk Management Johnson and Johnson Family of Companies
	Benefits/Risk Conclusions	**Stephen H. Zinner, MD** Charles S. Davidson Distinguished Professor of Medicine Harvard Medical School Past Chair, Department of Medicine Mount Auburn Hospital Cambridge, Massachusetts
	Conclusions	**Jeff Alder, PhD**
11:45 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:45 p.m.	**BREAK**	
3:00 p.m.	Questions to the Committee/Committee Discussion	
6:00 p.m.	**ADJOURNMENT**	